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JUL 01 2004

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the Radial Nail System.

Submitted By:	Wright Medical Technology, Inc.
Date:	April 9, 2004
Contact Person:	Ehab M Esmail
	Sr. Manager, Regulatory Affairs
Proprietary Name:	Radial Nail System
Common Name:	Radial Nail
Classification Name and Reference:	21 CFR 888.3030 Plate, Fixation, Bone – Class II
Device Product Code and Panel Code:	21 CFR 888.3030 Plate, Fixation, Bone – Class II

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The Radial Nail System is intended to be used for the fixation of unstable distal radius fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Failed fracture fixation with or without bone graft;
- Osteotomy and repair of distal radius malunion with or without bone graft;
- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone;
- Comminuted articular fractures, shearing fractures of the articular surface, severely comminuted extra-articular fractures, and fractures in which reduction has been lost following fixation with percutaneous pins with or without an external fixator.

B. DEVICE DESCRIPTION

The Radial Nail System consists of the following components: Radial Nail, Cortical Bone Screws, Buttress Pins and Screws. The design features of the components included in the Radial Nail System are summarized below:

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Radial Nail

- Universal in configuration – no lefts or rights
- Available in sizes 1-4
- Color anodized to match instrumentation for easy size identification

2.7 mm Cortical Bone Screws

- Lengths available: 12, 14, 16, 18, 20mm
- Color anodized to differentiate from 2.2mm buttress pins and 2.7mm buttress screws

2.2mm Buttress Pins

- Lengths available: 20, 22, 24, 26, 28, 30mm
- Color anodized to differentiate from 2.7mm cortical screws and 2.7mm buttress screws

2.7mm Buttress Screws

- Lengths available: 20, 22, 24, 26, 28, 30mm
- Color anodized to differentiate from 2.7mm cortical screws and 2.2mm buttress pins

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indication for use of the Radial Nail System is substantially equivalent to the previously submitted and cleared LOCON-T® Distal Radial Plating System. The safety and effectiveness of the Radial Nail System are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

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TM

Radial Nail System

INDICATIONS STATEMENT

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headquarters
Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone **www.wmt.com**
international subsidiaries
011.32.2.378.3905 Belgium **905.826.1600** Canada **011.33.1.45.13.24.40** France **011.49.4161.745130** Germany
011.39.0250.678.227 Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 1 2004

Ehab M. Esmail
Senior Manager, Regulatory Affairs
Wright Medical Technologies, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K040938
Trade/Device Name: Radial Nail System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: April 9, 2004
Received: April 12, 2004

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K040938

Device Name: Radial Nail System

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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